

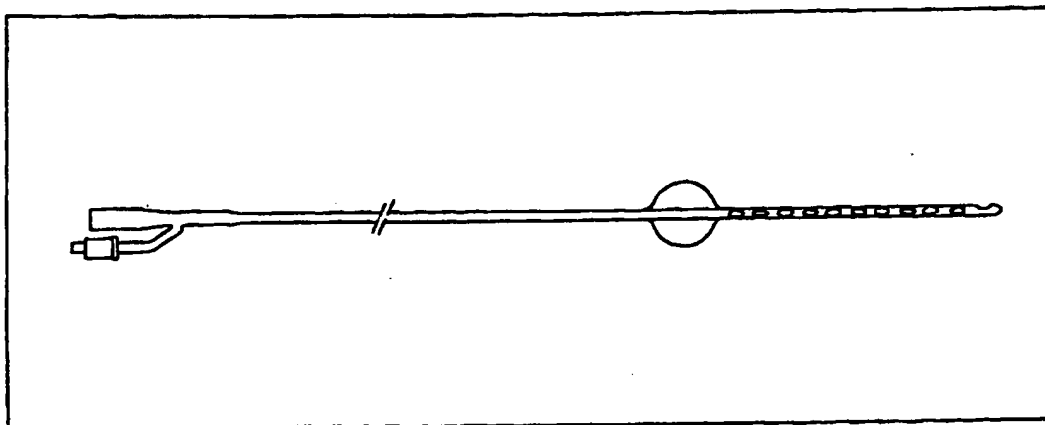
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(54) Title: DRAINAGE CATHETER FOR URINARY NEO-BLADDERS



(57) Abstract

A drainage catheter either for orthotopic urinary neo-bladders (anastomosis to the urethra), neo-bladders with stoma (anastomosis to the abdominal wall) or in enlargement entero-cistoplasties when the natural urinary bladder is enlarged utilizing different intestinal segments is disclosed. The catheter is characterized by the wide draining surface for urine preventing dangerous inadvertent obstructions of the neo-bladders in the post-operative period due to continuous formation of mucous cloths. This catheter also prevents and minimizes bleedings due to acid secretions.

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DRAINAGE CATHETER FOR URINARY NEO-BLADDERS

DESCRIPTION

TECHNICAL FIELD : SURGERY/UROLOGY

BACKGROUND ART

It is very common in the clinical practice the need to remove the urinary bladder in males, women, children, secondary to tumours, infections, neurologic abnormalities, or malformations.

Bladder trauma are also very frequent after a car crash, a working accident or other, and may require a cystectomy. The reconstruction of a new urinary bladder is common in the urologic practice utilizing different segments of the intestine or of the stomach.

Two fundamental types of urinary neo-bladders allow the patient to achieve the urinary continence: the orthotopic neo-bladders where the patient voids through the penis, helping himself with the contraction of the abdominal musculature, and as in the normal condition the continence is achieved with the natural sphincter ;

the neo-bladders with stoma in which the neo-bladder fashioned with a continence mechanism, is in communication with the abdominal wall, and the patient catheterizes himself

4 through a stoma to void regularly.

The common post-operative catheters utilized for the drainage of the neo-bladders are the same bladder catheters in use from many years to drain the natural bladder in several conditions (elderly condition, surgery of the

5 prostate, endoscopic or partial surgery of the bladder, etc...). The construction of a bladder (urethral) catheter is usually made with different materials (Latex Rubber, Polivinile, Poliurethane, Co-Polimer, Silicone Rubber, etc...) in different shapes and dimensions, has a large

6 diffusion all over the world and do not shows particular, technical difficulties. The balloon that anchors the catheter is made of the same rubber-elastic material in different sizes and volumes, depending from the finalities, and can be inflated o deflated through a continent valve inserted

7 tangential to the funnel of the catheter; the balloon can be fused to the catheter or simply stucked on it, depending on the technique.

The tip of a bladder catheter is very short, beeng about 3 cm.

- 8 Using the intestine in reconstructing the bladder, the intestinal mucosa is responsible of the frequent obstructions of the catheter by producing mucous secretions and mucous clots, with the risk of dangerous passive overdistensions of the neo-bladder just recently accomplished. The nurse personnel and the doctors must frequently wash the neo-bladders through the catheter along the two weeks of post-operative period.
- This is more and more important thinking that is impossible to leave a continuous washing flow through the catheter in the post-operative period, because a sudden and inadvertent obstructions not rapidly recognized by the medical and nursing staff, could determine a dangerous overdistension of the new fashioned bladder with possible rupture.
- Moreover, when a portion of the stomach has been utilized in reconstructing the bladder, a particular surgical procedure suitable for children, there is a production of Chloridric acid, digestive enzymes and mucous from the mucosa of the portion of the stomach utilized in the reconstruction.
- 12 The medical therapy cannot stop adequately the secretion of Chloridric acid that is sometimes responsible of severe bleedings from the mucosa (gastric) of the neo-bladders, often complained for a few months after the

neo-bladder procedure.

13 DISCLOSURE OF INVENTION

The use of a specific drainage catheter for neo-bladders that I invented, is indicated both for the orthotopic neo-bladders and the neo-bladders with stoma, either accomplished with the intestine or with the stomach.

14 Moreover, the specific catheter I invented for neo-bladders can be utilized to prevent the mucous obstruction when an enlargement cistoplasty of the natural bladder is performed with a segment of intestine.

This is obtained by the particular length of the tip,
15 and for a different positioning of the balloon from the apex of the catheter.

Moreover, the catheter is characterized by several holes along the tip of the catheter that allow a big surface of drainage; the catheter material warrants its
16 resistance to the mucous incrustation and to the acid secretions of the stomach.

Finally, for the specific design and the characteristics it is possible to wash and irrigate through the neo-bladder with extreme efficacy, removing the eventual mucous clots.

17 The Bladder catheters commonly in use have the tip, very short -measured from the distal end of the balloon to the apex of the catheter.

- The catheter I invented, specially projected for urinary neo-bladders has a very long functioning tip,
- 18 containing several holes to drain the urine and the mucous secretions produced by the mucosa of the intestine utilized in reconstructing the new bladder.
- The holes along the common bladder catheters are usually only three. The catheter I invented has several holes
- 19 regularly placed along the two opposite sides of the tip in alternate fashion with the same diameter and distance one to each other side to side.
- A bigger hole is positioned at the apex of the tip and it is the bigger one.
- 20 The specific, technical characteristic of the catheter I invented are the following ones:
- 1) The catheter can be made with the Latex Rubber Hydrogel coated or with Silicone Rubber materials, both fused and shaped.
- 21 If the catheter is made in Latex Rubber it is necessary, in order to improve its resistance to the incrustations and to improve a constant lubrication of the urethra for all the time in which the catheter is in place, that the catheter will be Hydrogel coated, a technique that in
- 22 commonly in use on other catheters from the market.

- If the catheter is made in silicone rubber, the catheter maintain more consistence and rigidity without losing too much the elasticity, and also the silicone make the catheter resistant to the incrustations from mucous and from the erosion by the acid secretions from the stomach when utilized, allowing to leave the catheter in place for a long time.
- 2) The following measurements are referred to a catheter of 22 French, the most commonly used in the clinical urologic practice.
- "French" is a common measurement unit for bladder catheters and follows this equation: $1 \text{ mm.} = 0,39 \text{ inches} = 3 \text{ French}$.
- A) The total length of the catheter is 52 cm.; partial measurements of this total are the following ones:
- the portion from the funnel(included) to the base of the balloon is 35 cm. The funnel is 4,5 cm.
- B) From the base of the balloon to the distal end of the balloon the length is 3 cm if the balloon is fused to the catheter. Depending on the technical modality of construction, the balloon can also be stucked to the catheter covering it for 3,5 cm. while the catheter maintains the same total length reported above of 52 cm.

- C) From the distal end of the balloon to the tip of the catheter the length is 14 cm.
- 27 3) The tip of the catheter is close at the apex, rounded acutely and 1 hole of 10 mm.X 4 mm. is placed posteriorly and superiorly to the apex.
- 4) The number of the holes placed along the surface of the tip (from the distal end of the balloon to the apex of the catheter measuring 14 cm. is divided as follow:
- 28 D) A total of 11 holes, 10 out of them measure 8 mm.X 3 mm.; 1 hole measures 10 mm.X 4 mm.
- E) - 5 holes are positioned on the left side of the catheter.
- 29 - 5 holes are positioned on the right side of the catheter, in alternate fashion to the contralateral.
- 1 hole is positioned posteriorly and superiorly at the apex of the catheter and measures 10 mm.X 4 mm.
- F) The distance between the opposite holes, from side to side of the catheter measures 1,6 cm.
- 30 5) The balloon has a volume of 30 cc., is made of the same material of the catheter and can be fused or stucked on it. (see point B).

- 31 6) The catheter has an external diameter(section) of 7,3 mm. (equal to 22 French, a conventional measurement unit of the catheters) for the whole lenght of the catheter excluding the funnel portion.
- 32 G) The catheter has at its internal two co-axial channels: the first channel is 3,7 mm. in diameter(except for the funnel portion), is shaped as a tunnel, and put in communication the two extremities of the catheter: the holes along the tip of the catheter with the funnel portion and then the outside.
- 33 The second channel is positioned in the thickness of the wall of the catheter just peripheral and co-axial to the first channel and measures 0,7 mm. in diameter.
- This thin channel put in communication a continent valve, with the balloon.
- 34 The continent valve is implanted for fusion tangential to the catheter and placed parallel to the funnel, with the balloon.
- The continent valve measures 6,5 cm. and generally for the 22 French catheters is about 1 cm. in the external diameter, depending from the type of valve already
- 35 existing taken from the market.

7) The first channel at the funnel end measures 7,5 mm. and can be connected to the common syringes for catheters of 60 ml. or 100 ml. funnel shaped in use to wash the bladder.

36 8) The catheter material (see point 1 of the description) is mixed with Barium Solphate in such a percentage that can make the catheter visible inside the neo-bladder with a conventional X-Rays equipment in the post-operative period. The catheter of my invention, even with large variations in sizes from the child to the adult (10 Fr.; 12 Fr.; 14 Fr.; 16 Fr.; 18 Fr.; 20 Fr.; 22 Fr.; 24 Fr. where "Fr." means "French" a common measurement unit of the catheters), can maintain the same configuration and the same shape following this equation $1 \text{ mm.} = 0,39 \text{ inches} = 3 \text{ French.}$

38 So, a new generation of post-operative catheters develops in different sizes for the adequate drainage of continent neo-bladders either orthotopic or with stoma.

BRIEF DESCRIPTION OF THE DRAWINGS

One drawing is presented, in three copies. The drawing show 39 the total design of the catheter, and point out the tip of the catheter with the several holes along its two sides, and the hole at the apex of the catheter, with the apex closed and rounded acutely.

Moreover, the drawing point out the balloon inflated,
40 the funnel end of catheter and the valve fused tangential
and parallel to it.

MODES FOR CARRYING OUT THE INVENTION

The technology in producing bladder catheters, is
well established all over the world by many
41 years, and the catheter I invented can be made with the
existing materials and technologies.

The novelty of the catheter I invented is in the particular
design, shape and dimensions that are thought and conceived
to be used to drain post-operatively the urinary neo-
42 bladders reconstructed in children and adults with the use
of the intestine or with the stomach. Differently, the
catheter actually used at this purpose are the common
bladder catheters neither specific nor affordables.

CLAIMS OF INVENTION

- 43 1) Drainage catheter for continent urinary neo-bladders accomplished with the intestine or with the stomach, 22 French in size(a common measurement unit of the catheters),made in Latex Rubber,Hydrogel coated, or made in Silicone Rubber, both materials fused and 44 shaped.This allows the post-operative drainage of mucous secretions and mucous clots from the intestine,and acid secretions from the stomach,when these organs are utilized for the urinary neo-bladder reconstruction.
- 2) Drainage catheter for continent urinary neo-bladders as 45 the first claim of invention,characterized by tip of 14 cm.(measured from the distal end of the balloon, to the apex of the catheter,out of 52 cm. of total lenght of the catheter.The very long tip of the catheter,is able to drain extremely well the mucous or acid secretions 46 when the intestine or the stomach are utilized to reconstruct the urinary neo-bladder.
- 3) Drainage catheter for continent urinary neo-bladders as the above claims of invention,characterized by the presence of 11 holes placed along the surface of the functional tip 47 of the catheter,10 holes out of 11 holes measure 8 mm. X 3mm.each one,and are placed in alternate

fashion on each lateral surface of the tip, 1 hole out of 11 holes measures 10 mm. X 4 mm., and is placed just posteriorly and anteriorly to the apex of the tip, that is closed and rounded acutely.

48

4) Drainage catheter for continent urinary neobladders as the above claims of invention, characterized by mixing Barium Solphate in such a percentage to the material of the catheter to make the catheter visible with a conventional X-Rays equipment in the post-operative period.

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5) Drainage catheter for continent urinary neo-bladders as the above claims of invention, characterized by a 30 cc. balloon made with the same material of the catheter, that can be fused or stucked on it.

50

6) Drainage catheter for continent urinary neo-bladders as the above claims of invention, characterized by a continent valve that allows to maintain the balloon inflated, to anchor the catheter to the body of the patient.

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7) Drainage catheter for continent urinary neo-bladders as the above claims of invention, that can widely change in measure from the child to the adult as follow : 10 Fr.; 12 Fr.; 14 Fr.; 16 Fr.; 18 Fr.; 20 Fr.; 22 Fr.; 24 Fr. ; maintaining the same configuration and the same shape, where "Fr." means "French" a common measurement unit of the

52 catheters.

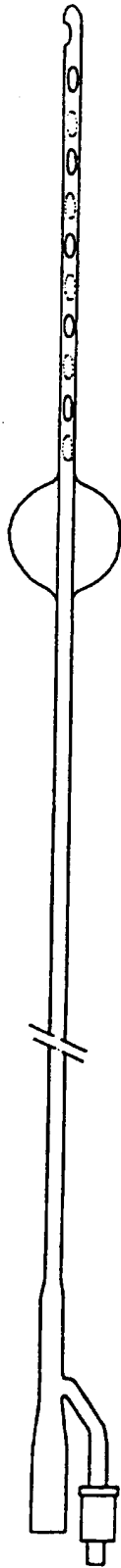


FIG. 1

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/IT 95/00143

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M27/00 A61M25/10 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61J A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 471 429 (COOK INC.) 19 February 1992	1-3,7
Y	see abstract; figures 1-5	4-6
Y	EP,A,0 381 042 (WILLY RUSCH AG) 8 August 1990 see abstract; claims 1-3; figure 1	5,6
Y	EP,A,0 483 941 (C.R.BARD, INC) 6 May 1992 see abstract; example 2	4
A	GB,A,2 123 300 (UROTEC, INC.) 1 February 1984	
A	US,A,3 993 080 (LOSEFF) 23 November 1976	
A	US,A,4 211 233 (LIN) 8 July 1980	
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☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>UROLOGE (B), vol. 26, 1986 SPRINGER-VERLAG, pages 186-188, V.LENT 'Einroll-Ballon-Silikonkatheter zur Suprapubischen Harnblasendrainage' see page 186; figures 1,2 -----</p>	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IT 95/00143

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-471429	19-02-92	US-A- 5041085 AU-B- 648288 AU-B- 7104891 JP-A- 4218168	20-08-91 21-04-94 29-08-91 07-08-92
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EP-A-483941	06-05-92	US-A- 5160790 AU-B- 7382291 JP-A- 5156203 US-A- 5290585	03-11-92 07-05-92 22-06-93 01-03-94
GB-A-2123300	01-02-84	CA-A- 1176929 DE-A- 3324747 FR-A,B 2530149 JP-B- 3044783 JP-A- 59022561	30-10-84 16-02-84 20-01-84 09-07-91 04-02-84
US-A-3993080	23-11-76	US-A- 3908664 CA-A- 1050377	30-09-75 13-03-79
US-A-4211233	08-07-80	NONE	

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